K120338

JUL 5 2012

510(k) Summary

Astra Tech Inc.
Atlantis™ Abutment and Atlantis™ Crown Abutment in Zirconia for Dentsply Ankylos Implant

ADMINISTRATIVE INFORMATION

510K Summary preparation date: July 5, 2012

Manufacturer Name:
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DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name: Atlantis™ Abutment and Atlantis™ Crown Abutment in Zirconia for Dentsply Ankylos Implant

Common Name: Endosseous dental implant abutment
21 CFR 872.3630

Product Code: NHA
Classification Panel: Dental Products Panel
Reviewing Branch: Dental Devices Branch

INTENDED USE

The Atlantis Abutment is intended for use with an endosseous implant to support a prosthetic device in a partially or completely edentulous patient. It is intended for use to support single and multiple tooth prosthesis, in the mandible or maxilla. The prosthesis can be cemented, screw retained or friction fit to the abutment. The abutment screw is intended to secure the abutment to the endosseous implant.

This device is compatible with the following manufacturers' implant systems:

The Atlantis Abutment in Zirconia for Dentsply Ankylos Implant is compatible with the Dentsply Ankylos 3.5mm, 4.5mm, 5.5mm and 7.0mm Implants.

The Atlantis™ Crown Abutment in Zirconia is intended for use with an endosseous implant to function as a substructure that also serves as the final restoration, in partially or completely edentulous patients. The prosthesis is screw retained. The abutment screw is intended to secure the crown abutment to the endosseous implant.

This device is compatible with the following manufacturers' implant systems:
the Dentsply Ankylos 3.5mm, 4.5mm, 5.5mm and 7.0mm Implants.

Please note: This device may be used in an early load situation, but is dependent on the specific implant system and protocol used by the dental professional.

Highly angled abutments on small diameter implants are intended for the anterior region of the mouth only.

The Atlantis Abutment is intended for use with an endosseous implant to support a prosthetic device in a partially or completely edentulous patient. It is intended for use to support single and multiple tooth prosthesis, in the mandible or maxilla. The prosthesis can be cemented, screw retained or friction fit to the abutment. The abutment screw is intended to secure the abutment to the endosseous implant.

DEVICE DESCRIPTION AND CLINICAL USE

The Atlantis Abutment and Atlantis™ Crown Abutment in Zirconia for Dentsply AnkylosImplant is compatible with the Dentsply Ankylos 3.5mm, 4.5mm, 5.5mm and 7.0mm Implants.

Please note: This device may be used in an early load situation, but is dependent on the specific implant system and protocol used by the dental professional.

Highly angulated abutments on small implants are to be used for the anterior region of the mouth only.

The devices covered in this submission are abutments which are placed into the dental implant to provide support for a prosthetic restoration. The subject abutments are for cemented, screw retained or friction fit restorations. The **Atlantis™ Abutment and Atlantis™ Crown Abutment in Zirconia for Dentsply Ankylos 3.5mm, 4.5mm, 5.5mm and 7.0mm Implants** is made of biocompatible material, yttria-stabilized tetragonal for the zirconia polycrystals (Y-TZP) (meets ISO Standards 6972 & 13356). Zirconia may have variation in shade. The **abutment screw** is made of Titanium grade Ti-6A1-4V ELI (meets ASTM Standard F-136). The zirconia abutments are placed over the implant shoulder and are mounted into the implant with a titanium screw.

EQUIVALENCE TO MARKETED DEVICE

Astra Tech Inc. demonstrated that, for purposes of the FDA's regulations of medical devices, the **Atlantis™ Abutment and Atlantis™ Crown Abutment in Zirconia for Dentsply Ankylos Implant** is substantially equivalent in indication and design principles to the Atlantis™ Abutment for Dentsply Ankylos Implant cleared under K#101004 which has been determined by FDA to be substantially equivalent to preamendment devices.

Table 1: Substantial Equivalence Summary

Technological Characteristics	**Atlantis™ Abutment and Atlantis™ Crown Abutment in Zirconia for Dentsply Ankylos Implant**	**Atlantis™ Abutment for Dentsply Ankylos Implant K#101004**
Material Composition	-Biocompatible ceramic material (abutment) - comparable compatible titanium grade Ti-6A-4V ELI material (screw assembly)	-comparable compatible titanium grade Ti-6A-4V ELI material
Performance characteristics	Allows the prosthesis to be cemented or screw retained to abutment. While the abutment screw is intended to secure the abutment to the endosseous implant.	Allows the prosthesis to be cemented or screw retained to abutment. While the abutment screw is intended to secure the abutment to the endosseous implant.
Intended Use	The Atlantis Abutment is intended for use with an endosseous implant to support a prosthetic device in a partially or completely edentulous patient. It is intended for use to support single and multiple tooth prosthesis, in the mandible or maxilla. The prosthesis can be cemented, screw retained or friction fit to the abutment. The abutment screw is intended to secure the abutment to the endosseous implant. This device is compatible with the following manufacturers' implant systems: The Atlantis Abutment in Zirconia for Dentsply Ankylos Implant is compatible with the Dentsply Ankylos 3.5mm, 4.5mm,	The Atlantis Abutment is intended for use with an endosseous implant to support a prosthetic device in a partially or completely edentulous patient. It is intended for use to support single and multiple tooth prosthesis, in the mandible or maxilla. The prosthesis can be cemented, screw retained or friction fit to the abutment. The abutment screw is intended to secure the abutment to the endosseous implant. The Atlantis™ Crown Abutment in Zirconia is intended for use with an endosseous implant to function as a substructure that also serves as the final restoration, in partially or completely edentulous patients. The prosthesis is screw retained.

Intended Use (continued)	5.5mm and 7.0mm Implants. The Atlantis™ Crown Abutment in Zirconia is intended for use with an endosseous implant to function as a substructure that also serves as the final restoration, in partially or completely edentulous patients. The prosthesis is screw retained. The abutment screw is intended to secure the crown abutment to the endosseous implant. This device is compatible with the following manufacturers' implant systems: the Dentsply Ankylos 3.5mm, 4.5mm, 5.5mm and 7.0mm Implants. Please note: This device may be used in an early load situation, but is dependent on the specific implant system and protocol used by the dental professional. Highly angled abutments on small diameter implants are intended for the anterior region of the mouth only.	The abutment screw is intended to secure the crown abutment to the endosseous implant.
Device Description and Clinical Use	The Atlantis Abutment and Atlantis™ Crown Abutment in Zirconia for Dentsply Ankylos	The Atlantis Abutment and Atlantis™ Crown Abutment in Zirconia for Dentsply Ankylos Implant is compatible with the

	Implant is compatible with the Dentsply Ankylos 3.5mm, 4.5mm, 5.5mm and 7.0mm Implants. Please note: This device may be used in an early load situation, but is dependent on the specific implant system and protocol used by the dental professional. Highly angulated abutments on small implants are to be used for the anterior region of the mouth only. The devices covered in this submission are abutments which are placed into the dental implant to provide support for a prosthetic restoration. The subject abutments are for cemented, screw retained or friction fit restorations.	Dentsply Ankylos 3.5mm, 4.5mm, 5.5mm and 7.0mm Implants. Please note: This device may be used in an early load situation, but is dependent on the specific implant system and protocol used by the dental professional. Highly angulated abutments on small implants are to be used for the anterior region of the mouth only. The devices covered in this submission are abutments which are placed into the dental implant to provide support for a prosthetic restoration. The subject abutments are for cemented, screw retained or friction fit restorations.
Dimensions and Angulation	Abutment sizes: 3.5mm, 4.5mm, 5.5mm and 7.0mm Atlantis Abutments design only allows for geometry within the following limits: -Angles up to 30 degrees from the implant axis -Widths up to 6.5 mm from the implant axis -Heights (length) up to 15 mm from the implant interface	Implant sizes: 3.5mm, 4.5mm, 5.5mm and 7.0mm Atlantis Abutments design only allows for geometry within the following limits: -Angles up to 30 degrees from the implant axis -Widths up to 6.5 mm from the implant axis -Heights (length) up to 15 mm from the implant interface

Summary of Non-clinical Testing

Static and fatigue compression testing was conducted on "worst case scenario" implant assemblies using Atlantis angled zirconia abutments with the Dentsply Ankylos Implant. Test results demonstrated that the Atlantis Abutments and Atlantis Crown Abutments are compatible with the Dentsply Ankylos Implant and the implant system supported appropriate static and fatigue test loads demonstrating that the implant system performs as intended.

Conclusion for Substantial Equivalence:

The **Atlantis™ Abutment and Atlantis™ Crown Abutment in Zirconia for Dentsply Ankylos Implant** is substantially equivalent to the Atlantis™ Abutment for Dentsply Ankylos Implant K#101004 predicate device based on noted similarities in indication, manufacturing material, generated design principle and performance characteristics data.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Astra Tech, Incorporated
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Regulatory Consultant
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JUL 5 2012

Re: K120338
Trade/Device Name: Atlantis™ Abutment and Atlantis™ Crown Abutment in Zirconia for Dentsply Ankylos Implant
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: June 9, 2012
Received: June 12, 2012

Dear Ms. Brown:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known) K120338

Device Name: Atlantis™ Abutment and Atlantis™ Crown Abutment in Zirconia for Dentsply Ankylos Implant

Indication for Use:

The Atlantis Abutment is intended for use with an endosseous implant to support a prosthetic device in a partially or completely edentulous patient. It is intended for use to support single and multiple tooth prosthesis, in the mandible or maxilla. The prosthesis can be cemented, screw retained or friction fit to the abutment. The abutment screw is intended to secure the abutment to the endosseous implant.

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Prescription Use___X____ AND/OR Over-the-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for MSR

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K120338